Featured Clinical Research

Comparison of Safety and Efficacy of CYPHER® Stent and ENDEAVOR® Stent in Patients with Acute ST Elevation Myocardial Infarction(STEMI) undergoing emergency PCI and Analysis of Current Status of Emergency PCI Green Channel in China

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Background: To compare the Safety and Efficacy of CYPHER® Sirolimus Stent and ENDEAVOR® Zotarolimus Stent in Patients with Acute STEMI undergoing emergency PCI, and to analysis Current Status of Emergency PCI Green Channel for Patiens with STEMI in China.

Methods: 1020 patients were to be randomized, these patients were STEMI within 12 hours preparing emergency PCI, with "De novo"lesions in native coronary arteries, and informed consent were written. and 145 cases were exclused(14.2%), totally 875 patients entered the study, 449 patients in ENDEAVOR group and 426 patients in CYPHER group, totally 761 patients (86.9%) with 6-months Clinical follow-up. The primary endpoints were cardiac mortality, myocardial infarction, and target lesion revascularization (TLR) at 6 months.

Results: The Baseline Clinical Characteristics and Lesion Characteristics between 2 groups were no significant, Myocardial Infarction at 6 months between 2 groups were 2and 3(P =0.61),Stent Thrombosis at 6 months between 2 groups were both 2 cases(P =0.96),Stent restenosis at 6 months between 2 groups were 5 and 1(P=0.09),Target Lesion Revascularization at 6 months at 6 months between 2 groups were 6 and 3(P =0.35),Cardiac death at 6 months were 12 and 9(P =0.56),Composite MACE at 6 months at 6 months were 20(4.5%)and 15(3.5%),P =0.48. The analysing of Emergency Green Channel showed that the mean time of door to ballon was 119.2±80.1 minutes (40~710 min), and only 47.6% patients whose D T B time was less than 90 minutes.

Conclusion: 1. There was no signal differential profile between Cypher and Endeavor during 6 months in safety and efficacy. The antirestenotic efficacy of Endeavor was somewhat inferior to the Cypher stent in Patients with STEMI undergoing emergency PCI at 6-month follow-up. 2.Currently, AMI patients of Chinese first class hospital are treated delayed seriously. There is still a big gap with PCI Guide which require 90min from door to balloon.

Baseline Clinical Characteristics

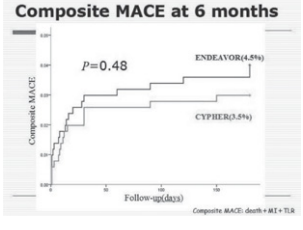
	END	CYP	P
Age(yrs)	59.6	60.2	NS
Women(%)	18.4	18.2	NS
Diabetes(%)	16.7	19.4	NS
Hypertension(%)	48.0	51.6	NS
Current smoker (%)	58.8	55.1	NS
Hypercholesterolemia (%)	18.2	17.3	NS
Previous MI(%)	2.5	2.0	NS
Anterior MI(%)	48.8	50.9	NS
EF(%)	56.3±9.9	54.4±9.3	NS

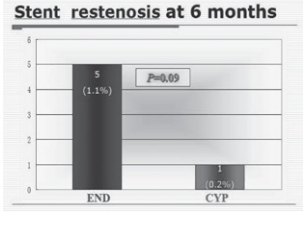
Lesion Characteristics

	END	CYP	P
LAD(%)	49.0	44.5	NS
LCX(%)	14.2	17.5	NS
RCA(%)	36.8	38	NS
TIMI 0(%)	65.4	60.4	0.08
Heavy thrombus(%)	63.6	64.1	NS
Lesion type A (%)	10.8	11.5	NS
Lesion type B (%)	50.9	55.6	NS
Lesion type C (%)	38.3	32.9	NS

PCI Information

	END	CYP	P
Radial(%)	53.1	52.4	NS
IABP(%)	5.9	6.3	NS
2b/3a(%)	51.8	53.9	NS
Stents (n)	1.44±0.6	1.35±0.6	0.03
Stent length (mm)	24.1±5.6	24.7±6.2	0.03
Stent diameter (mm)	3.1±0.4	3.1±1.1	NS
Eelective PCI(%)	12.4	14.9	NS





Long-term Clinical Results from the All-comers LEADERS Trial: 4 Year Follow-up Data.

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Background: There is concern of an increased incidence of very late stent thrombosis, associated with early generation DES potentially related to the durable polymer. The Biolimus A9™ eluting stent platform (BES) releases biolimus from an abluminal biodegradable polymer, polylactic acid (PLA), which is fully absorbed after 6-9 months. The LEADERS trial aimed to compare the safety and efficacy of BES with an established stent platform releasing sirolimus from a durable polymer (SES) in a large scale, all-comers, non-inferiority trial. The purpose of this presentation is to present the 4- year follow-up data to determine whether there are differences between the biodegradable BES platform as compared to the durable polymer SES platform.

Methods: LEADERS is a multi-center, randomized, assessor-blind, non-inferiority trial performed at 10 European sites in an all-comers, "real world" patient population without limitation with respect to lesion length, number of treated lesions or vessels as well as clinical indication (chronic stable angina vs. acute coronary syndromes). A total of 1,707 patients were enrolled and randomly allocated 1:1 to BES or SES. The primary endpoint was MACE (a composite of cardiac death, MI, or clinically-indicated TVR) at 9 months. Secondary endpoints include death, cardiac death, MI, ST (ARC defined), TLR and TVR. All patients are followed up to 5 years.

Results: BES sustained its non-inferiority to SES in terms of the primary endpoint of MACE up to 4 year follow-up with a trend towards improved outcomes at 4 years (18.7% for BES vs. 22.6% for SES, RR (95% CI): 0.81 (0.66 to 1.00), p non-inf<0.0001,psup=0.051). Very late definite stent thrombosis (0.4% for BES vs. 1.8% for SES, RR(95% CI): 0.20 (0.06 to 0.67), psup=0.004) as well as very late definite/ probable stent thrombosis (0.7% for BES vs. 2.4% for SES, RR (95% CI): 0.29 (0.12 to 0.73), psup=0.005) were less frequent with BES than SES at 4 years. The 4 year outcomes are summarized in table 1.

Conclusion: Our results suggest that BES represents a safe and effective alternative to SES with robust clinical results up to 4-year follow-up.

Table 1. LEADERS 4-year outcomes

Outcome	BES (N=857)	SES (N=850)	Risk Ratio (95% CI)	p value[1]
MACE[2]	160 (18.7%)	192 (22.6%)	0.81 (0.66 to 1.00)	**0.051**
Cardiac Death	51 (6.0%)	57 (6.7%)	0.88 (0.60 to 1.29)	0.514
MI	71 (8.3%)	73 (8.6%)	0.96 (0.69 to 1.33)	0.803
clinically-indicated TVR	91 (10.6%)	110 (12.9%)	0.80 (0.61 to 1.06)	0.122
Definite ST	20 (2.3%)	32 (3.8%)	0.62 (0.35 to 1.08)	0.086
Very Late Definite ST	3 (0.4%)	15 (1.8%)	0.20 (0.06 to 0.67)	**0.004**
Definite/Probable ST	29 (3.4%)	39 (4.6%)	0.73 (0.45 to 1.19)	0.204
Very Late Definite/Probable ST	6 (0.7%)	20 (2.4%)	0.29 (0.12 to 0.73)	**0.005**

1. p values for superiority
2. MACE: a composite endpoint of cardiac death, MI and clinically-indicated TVR

Two-year results from a Randomized Comparison of Everolimus-Eluting and Sirolimus-Eluting Stents in Patients Treated with Percutaneous Coronary Intervention (SORT OUT IV Trial)

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Background: The sirolimus-eluting stent has demonstrated the least amount of late lumen loss among previously released drug-eluting stents, but its long-term safety and efficacy have not been compared head-to-head with the next-generation everolimus-eluting stent

Methods: The Scandinavian Organization for Randomized Trials with Clinical Outcome (SORT OUT) IV was a randomized multicenter, open-label, all-comer, two-arm, non-inferiority trial comparing the everolimus-eluting stent with the sirolimus-eluting stent in patients with coronary artery disease. The primary end point was a composite of safety (cardiac death, myocardial infarction, definite stent thrombosis) and efficacy (target vessel revascularization) parameters. Intention-to-treat analyses were done at 9-month (primary end point) and two-year follow-up.

Results: 1,390 patients were assigned to receive the everolimus-eluting stent, and 1,384 patients were assigned to receive the sirolimus-eluting stent. At 9-month follow-up, 68 [4.9%] patients treated with the everolimus-eluting stent versus 72 [5.2%] patients treated with the sirolimus-eluting stent experienced the primary end point (hazard ratio (HR) = 0.94; 95% confidence interval (CI): 0.67 to 1.31) (p for non-inferiority = 0.01). Two-year results will be available at the presentation.

Conclusion: Two-year results will be available at the presentation.

Clinical Evaluation of the IN.PACT Drug-eluting Balloon for Treatment of Femoro-popliteal Arterial Disease: Twelve Month Results from a Multicenter Italian Registry

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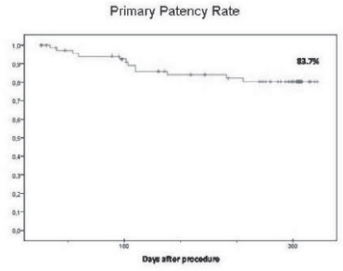
Background: This study evaluated the use of a drug-eluting balloon (DEB) for treatment of femoropoliteal arterial disease.Conventional balloon angioplasty and stenting in this setting is associated with a high restenosis rates within
12 months post-procedure. Recent data suggest that use of DEBs may reduce restenosis. Twelve month outcomes following DEB use with provisional stenting are described.

Methods: This prospective registry enrolled patients (Rutherford class 2, 3, or 4) with reference vessel diameter of 3 to
7 mm and lesion/occlusion length ≤15 cm. Endpoints included primary patency rate, target lesion revascularization (TLR), and changes in Rutherford class and ankle-brachial index (ABI). Walking capacity, absolute claudication distance (ACD), and quality of life (QOL) were also assessed

Results: At 12 months follow-up, 92/105 patients (87.6%) were evaluable. Baseline ABI was 0.56 ± 0.15. Baseline Rutherford classification was 26.7% for class 2 and 64.8% for class 3. Most lesions were located in the superficial femoral artery (77.1%).

Mean lesion length was 76.3 ± 38.3 mm; 29.8% of lesions were total occlusions. The device was successfully utilized in all patients and only 12.3% of lesions required stenting. At 12 months the primary patency rate was 83.7%, the TLR rate was 7.6%, 85.6% of patients were Rutherford class 0 or 1, and the mean ABI was 0.86 ± 0.15. QOL and ACD significantly improved post procedure.

Conclusion: Use of a DEB for treatment of femoropopliteal arterial disease resulted in consistent clinical improvement across multiple endpoints with a low rate of stenting and TLR.



Efficacy and Safety of Bivalirudin Compared to Unfractionated Heparin Among Patients Undergoing Balloon Aortic Valvuloplasty: a Two-Center Registry.

George Dangas, Annapoorna Kini, Jennifer Yu, Mauricio Cohen, Brian O'Neill, Shyam Poludasu, Christopher Varughese, Evan Jacobs, David Knopf, Vikas Singh, Jason Kovacic, Robert Pyo, Pedro Moreno, Usman Baber, Roxana Mehran, Samin Sharma

Background: With transcatheter aortic valve replacement (TAVR) on the horizon, balloon aortic valvuloplasty (BAV) procedures have increased. A major limitation of both BAV and TAVR is vascular and bleeding complications, with 30- day rates of 11.0% and 9.3% respectively following TAVR reported in the recent PARTNER trial. This is partially due to the patient population, and the large caliber arterial access needed for these procedures. Bivalirudin (BIV) has been shown to reduce bleeding complications compared to unfractionated heparin (UFH) after PCI. Furthermore, the "preclosure" technique with a suture-based closure device (VCD) has been reported to achieve hemostasis after procedures with large caliber arterial sheaths. Clinical outcomes with BIV, UFH and VCD in BAV procedures have not been previously reported. We therefore aimed to evaluate the safety and feasibility of BIV vs. UFH in BAV.

Methods: We identified 508 consecutive pts undergoing BAV at 2 tertiary referral centers. All pts were identified from 1/1/2005 to 12/31/2010. Baseline, clinical, and angiographic data were extracted by an independent team. All major cardiovascular and bleeding events were identified, source documented, and adjudicated by an independent CEC. Clinical follow up was performed up to 30-days post procedure. All emergent BAV procedures were excluded. Univariate and multivariate logistic regression models were used to evaluate associations between baseline characteristics, BIV vs. UFH use, and VCD vs. manual compression use, in reference to in-hospital and 30-day outcomes. The primary endpoint of the study was incidence of BARC ≥3 bleeding. Major secondary endpoints included: MACE, stroke, CV and all-cause mortality, as well as bleeding scales according TIMI major/minor, and VARC definitions.

Results: Complete data on all consecutive patients according to BIV and VCD will be available for presentation.

Conclusion: This two center registry comprises the largest clinical data on BAV with BIV and the first report of BARC, VARC, and TIMI bleeding scale comparison in this arena.

One-Year Outcomes after Implantation of XIENCE PRIME and XIENCE PRIME Long Lesion stents in Patients with Coronary Artery Disease: Primary Endpoint Results of the SPIRIT PRIME Multicenter Clinical Trial

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Background: The XIENCE V everolimus-eluting stent (EES, Abbott Vascular, Santa Clara, CA) demonstrated superior efficacy and long term safety in the SPIRIT clinical trials series. The next generation XIENCE PRIME EES includes
2.25 mm diameters and 33 and 38 mm lengths to treat small vessels and long lesions (LL). The SPIRIT PRIME trial aimed to show clinical equivalence of the XIENCE PRIME and XIENCE V stents.

Methods: SPIRIT PRIME, a prospective, non-randomized clinical trial with two separate arms, tested the XIENCE PRIME core sizes and LL (33 and 38 mm) stents. The primary endpoint is 1-year target lesion failure (TLF; cardiac death, target vessel myocardial infarction [TV-MI] or clinically indicated target lesion revascularization [CI-TLR]) compared to pre-specified performance goals based on historical data according to FDA requirements. The Core Size Registry (CSR) analyzed 401 patients and the Long Lesion Registry (LLR) 104 patients. Treatment of up to 2 de novo lesions in different epicardial vessels was allowed. Data were fully monitored and all endpoint events adjudicated by an independent committee.

Results: There were 447 CSR and 124 LLR lesions treated and a total of 530 XIENCE PRIME and 105 XIENCE PRIME LL stents implanted. Clinical device success rates were 98.2% (CSR) and 97.6% (LLR). Female and diabetic subjects were 29.7% and 34.9%, respectively in the CSR and 37.5% and 35.6%, respectively in the LLR. In both arms, the primary endpoint was met by all analyses. The Table shows 1-year outcomes.

Conclusion: The SPIRIT PRIME study demonstrated 1-year safety and efficacy of the new XIENCE PRIME EES with low cardiac death, MI and CI-TLR rates in core size and LL cohorts, suggesting clinical equivalence of the XIENCE PRIME stent to XIENCE V.

Table: SPIRIT PRIME Primary and Secondary Endpoint Results

Primary Endpoint Core Size Registry	XIENCE PRIME Observed Rate (N=401)	Performance Goal	Upper Limit of One-sided 95% Confidence Interval	P-Value[1]
1 Year TLF (per protocol)	4.5% (18/399)	≤9.2% (per protocol)	6.6%	0.0003
1 Year TLF (per ARC)	6.5% (26/399)	≤15.3% (per ARC)	8.9%	<0.0001
1 Year TLF (per ARC)	6.5% (26/399)	≤9.2% (per protocol)	8.9%	0.0338
Primary Endpoint Long Lesion Registry	**XIENCE PRIME Observed Rate (N=104)**	**Performance Goal**	**Upper Limit of One-sided 95% Confidence Interval**	**P-Value[1]**
1 Year TLF (per protocol)	7.7% (8/104)	≤19.2% (per protocol)	13.5%	0.0009
1 Year TLF (per ARC)	12.5% (13/104)	≤26.0% (per ARC)	19.1%	0.0006
1 Year TLF (per ARC)	12.5% (13/104)	≤19.2% (per protocol)	19.1%	0.0484
Secondary Endpoints		**XIENCE PRIME Observed Rate CSR (N=401)**	**XIENCE PRIME Observed Rate LLR (N=104)**	
Cardiac Death		0.3% (1/399)	0.0% (0/104)	
All MI (per protocol)		1.8% (7/399)	4.8% (5/104)	
All MI (per ARC)		4.5% (18/399)	10.6% (11/104)	
TV-MI (per protocol)		1.8% (7/399)	4.8% (5/104)	
TV-MI (per ARC)		4.0% (16/399)	10.6% (11/104)	
CI-TLR		2.5% (10/399)	2.9% (3/104)	
ARC-Defined Stent Thrombosis (Definite/Probable)		0.5% (2/399)	0.0% (0/104)	

Notes:
- N is the total number of subjects.
- Population for SPIRIT PRIME consists of those subjects who were treated with at least one PRIME stent and had cardiac enzyme data between 8 hour post index procedure and hospital discharge.
- TLF includes cardiac death, target vessel MI or clinically indicated TLR.
- Time Frame includes follow-up window (365 + 28 days).
- Primary endpoint TLF from hierarchical counts; Secondary Endpoints from non-hierarchical counts.
- ARC: Academic Research Consortium
- [1] One-sided p-value against pre-specified performed goals, to be compared at a 0.05 significance level.

SeQuent Please World Wide Registry: Paclitaxel eluting balloon angioplasty in routine real world practice in a large patient population

Jochen Wöhrle

Background: The paclitaxel eluting SeQuent Please balloon catheter (B.Braun Melsungen AG, Germany) has shown to be superior to plain balloon angioplasty for treatment of in-stent restenosis (ISR) in bare-metal stents (BMS) and in drug-eluting stents (DES). Furthermore, paclitaxel eluting balloon angioplasty reduced angiographic and clinical restenosis in de-novo lesions after endothelial progenitor cell capturing stenting. However, in these trials number of patients was limited and inclusion criteria were restricted to a pre-defined lesion subset.
Therefore, we performed the SeQuent Please World Wide Registry in order to get the results of paclitaxel eluting balloon angioplasty in a large sized registry without limitation to a special patient population.

Methods: 2098 patients with 2359 lesions treated with SeQuent Please paclitaxel eluting balloon angioplasty were included in 75 centres from 8 countries. Patients are clinically followed. The primary endpoint is the clinically driven target lesion revascularization rate (TLR) at 9 month. Secondary clinical endpoints are target vessel revascularization, vessel thrombosis according to ARC criteria, major adverse cardiac events as a composite of cardiac death, TLR and myocardial infarction related to the target vessel.

Results: Patients were included due to treatment of ISR in BMS (38%), ISR in DES (23%), ISR in DES/BMS (10%) or de-novo lesions (29%). Patients suffered from STEMI/NSTEMI in 17% and from unstable angina in 39%. Frequency of diabetes mellitus was high with 35%. Treatment location included LAD (40%), CX artery (24%), RCA (31%) but also saphenous vein grafts (5%). Balloon length ranged from 10-30mm, balloon diameter from 2.0-4.0mm. Antiplatelet therapy with aspirin was mainly combined with clopidogrel (96%) but also with prasugrel (4%) and ranged from 3-12 months. Nine months follow-up will be completed in September 2011.

Conclusion: Clinical 9 months data including the primary endpoint (clinically driven TLR) will be presented for the first time.

The Mechanism Of Stent Thrombosis (MOST) study.

Guido Parodi, Alessio La Manna, Marco Valgimigli, Massimo Fineschi, Vito Ramazzotti, Benedetta Bellandi, Giampaolo Niccoli, Renato Valenti, David Antoniucci, Francesco Prati

Background: Stent thrombosis (ST) may occur late after stent implantation, and its cause remains unknown. The use of Optical Coherence Tomography (OCT) in patients with ST is a valid approach to understand the impact of stent related features that can lead to ST. We sought to assess by OCT stent strut coverage and malapposition after thrombectomy in consecutive patients presenting with ST.

Methods: The Mechanism Of Stent Thrombosis (MOST) Study was a prospective multicentre non-randomized registry that enrolled 23 (6 subacute, and 17 late or very late) ST patients between January 2010 and July 2011. The included patients were matched (1:1) with control subjects who had OCT stent assessment at the same Core Lab, during the same time period, at the same time interval from stent implantation. Blinded OCT analyses were done in all cases in a validated core lab (RHR, Rome). The 2 study groups were similar in all the baseline characteristics.

Results: Overall, 16,367 and 13,047 struts were analysed in the ST and in the matched group, respectively. Patients with ST showed a higher rate of uncovered and malapposed struts as compared with the control group (table). All patients with ST had previously discontinued dual antiplatelet therapy (n=14) or showed high residual platelet reactivity on clopidogrel therapy.

Conclusion: Patients with stent thrombosis showed a higher rate of uncovered and malapposed stent struts as compared with control subjects. High platelet reactivity seems a necessary co-factor.